



Monoclonal Antibodies for COVID-19: The Clinical Evidence

Monoclonal antibodies are laboratory-produced proteins that act as substitute antibodies to restore, enhance, or mimic the immune system's attack on cells. Given the novel nature of SARS-CoV-2, the virus that causes COVID-19, the science is evolving rapidly. This information sheet provides the latest clinical evidence available.

CLINICAL TRIALS AND FDA EMERGENCY USE AUTHORIZATIONS (EUA)

As of May 17, 2021, the following monoclonal antibodies have been authorized by the FDA for emergency use:

- **REGEN-COV™ (casirivimab and imdevimab)¹**
- **Bamlanivimab and etesevimab²**

The NIH COVID-19 Treatment Guidelines Panel recommends (AIIa) using one of these combination anti-SARS-CoV-2 monoclonal antibodies to treat outpatients with mild to moderate COVID-19 who are at high risk of clinical progression, as defined by the Emergency Use Authorization.³

Rating of Recommendations:

A = Strong; **B** = Moderate; **C** = Optional

Rating of Evidence:

- I** = One or more randomized trials without major limitations
- IIa** = Other randomized trials or subgroup analyses of randomized trials
- IIb** = Nonrandomized trials or observational cohort studies
- III** = Expert opinion

REGEN-COV (Casirivimab and Imdevimab)¹:

Reduced Viral Load, ER Visits, and Hospitalization

"The **largest reductions in viral load** relative to **placebo occurred in patients with high viral load** (-0.78 log₁₀ copies/mL) or who were seronegative (-0.69 log₁₀ copies/mL) at baseline. Reductions occurring from Day 1 through Day 11 were similar to those for Day 1 through Day 7."⁴

"When considering only individuals at high risk for progression to severe disease, [...] **hospitalization or emergency room visits were reported in 9% of participants in the placebo group compared to 3% in the combined casirivimab and imdevimab dose groups**"⁴ – a 70% relative reduction.

— FDA-authorized Fact Sheet for Healthcare Providers (May 17, 2021): Phase 1 and 2 data from an ongoing trial R10933-10987-COV-2067; data from 799 symptomatic patients.





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Bamlanivimab and Etesevimab²:

Reduced Viral Load, Hospitalization, and Death

“[...] COVID-19 related hospitalization [...] or death [...] occurred in 15 subjects treated with placebo (6%) as compared to 4 events in subjects treated with bamlanivimab 700 mg and etesevimab 1,400 mg together (0.8%), an 87% [relative] reduction. There were 4 deaths in subjects treated with placebo and no deaths in subjects treated with bamlanivimab 700 mg and etesevimab 1,400 mg together [...].”⁵

“The median time to sustained symptom resolution [...] was 8 days for subjects treated with bamlanivimab 700 mg and etesevimab 1,400 mg together as compared with 10 days for subjects treated with placebo [...].”⁵

— FDA-authorized Fact Sheet for Healthcare Providers (May 14, 2021): Phase 3 Data from BLAZE-1 (bamlanivimab 700 mg and etesevimab 1,400 mg) trial; Bamlanivimab and etesevimab at the authorized doses of 700 mg and 1,400 mg have been administered together to approximately 800 subjects in clinical trials to participants at high risk for progression to severe COVID-19 disease.

For more information, visit
CombatCOVID.hhs.gov

English: 1-877-332-6585 • Spanish: 1-877-366-0310



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References

1. Office of the Commissioner. (2021, February 25). REGEN-COV (Casirivimab and Imdevimab) Emergency Use Authorization Letter of Authorization (LOA). U.S. Food and Drug Administration. <https://www.fda.gov/media/145610/download>
2. Office of the Commissioner. (2021, February 25). Bamlanivimab and Etesevimab Emergency Use Authorization Letter of Authorization (LOA). U.S. Food and Drug Administration. <https://www.fda.gov/media/145801/download>
3. Statement on Anti-SARS-CoV-2 Monoclonal Antibodies EUA. (2021, April 21). COVID-19 Treatment Guidelines. <https://www.covid19treatmentguidelines.nih.gov/statement-on-anti-sars-cov-2-monoclonal-antibodies-eua/>
4. Fact Sheet for Healthcare Providers Emergency Use Authorization (EUA) of REGEN-COV (casirivimab and imdevimab; revised May 17, 2021) <https://www.fda.gov/media/145611/download>
5. Fact Sheet for Healthcare Providers Emergency Use Authorization (EUA) of bamlanivimab and etesevimab (revised May 14, 2021) <https://www.fda.gov/media/145802/download>